UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	CIVIL ACTIONS NOS. 02-3779 (JWB) 02-4537 (JWB) (Chief Judge John W. Bissell) **DOCUMENT FILED ELECTRONICALLY** **ARGUMENT DATE: NOVEMBER 22, 2004**

PLAINTIFF'S MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION *IN LIMINE* TO PRECLUDE EVIDENCE OF OBJECTIVE CONSIDERATIONS OF NON-OBVIOUSNESS AS IRRELEVANT UNDER FEDERAL RULES OF EVIDENCE 401-403

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INTRODUCTION

Plaintiff SmithKline Beecham Corp. ("SKB") is the owner of a patent covering the antiepileptic drug lamotrigine. Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a generic drug maker seeking to market lamotrigine before SKB's patent expires. Teva has stipulated that its marketing will infringe various claims of SKB's patent. (Docket Item 39). Thus, the only issue left for trial is whether Teva can prove by clear and convincing evidence that the infringed patent claims are invalid.

Teva alleges that some of these patent claims are invalid for obviousness-type double patenting. By its motion, Teva would have this Court make that determination in a factual vacuum, ignoring the substantial evidence that SKB will introduce concerning secondary considerations of non-obviousness, also called "real world" evidence,[1] "objective indicia", "objective considerations" or "objective criteria". Such evidence here includes the unquestionable commercial success of lamotrigine in the treatment of epilepsy (over 5 million prescriptions written in the United States alone), and the fact that the other three generic drug makers seeking to market lamotrigine have not even attempted to challenge the validity of SKB's patent. While it is readily apparent why Teva seeks to preclude this powerful evidence of non-obviousness, there is no basis in the law for doing so. Contrary to Teva's assertions, evidence of secondary considerations is relevant to obviousness-type double patenting. Incredibly, Teva also seeks to preclude under the rubric of "secondary considerations" evidence of "unexpected results", such as lamotrigine's superior anticonvulsant properties. However, under binding precedent, a compound cannot be

[1] *See Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1577 (Fed. Cir. 1987).

separated from its properties, which are a *primary* consideration that must be examined in any obviousness analysis. Accordingly, Teva's motion should be denied.

ARGUMENT

1. Secondary Considerations Are Relevant To Obviousness-Type Double Patenting

A patent claim is invalid for obviousness-type (or "nonstatutory") double patenting only if it is "obvious over, or anticipated by" an earlier-expiring claim in a commonly owned patent. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001) (*en banc*). Where, as here (Teva Br. at 1), the obviousness-type double patenting allegation is based on a theory of obviousness, rather than anticipation, courts long have used a test analogous to the one for statutory obviousness under 35 U.S.C. § 103. *See, e.g., In re Braat*, 937 F.2d 589, 592-593 (Fed. Cir. 1991); *In re Bartfeld*, 925 F.2d 1450, 1453 (Fed. Cir. 1991). The tests are analogous insofar as both involve an examination of the secondary considerations of non-obviousness set forth by the United States Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 17 (1966), such as the commercial success of the invention, a long-felt but unfulfilled need for the invention, and acquiescence by others in the validity of the patent.

These secondary considerations are relevant to obviousness-type double patenting. *See, e.g., Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.*, 784 F.2d 351, 355 (Fed. Cir. 1986) (finding no obviousness-type double patenting based on absence of evidence relating to *Graham* considerations); *American Cyanamid Co. v. United States Surgical Corp.*, 833 F. Supp. 92, 127 (D. Conn. 1992); *Mirafi v. Murphy*, 1989 U.S. Dist. LEXIS 16399 at *40-44 (D.N.C. Oct. 23, 1989), *aff'd in part, rev'd in part by* 1991 U.S. App. LEXIS 1636 (Fed. Cir. Feb. 4, 1991). Indeed, such considerations, when present, *must* be considered. *See*

Panduit, 810 F.2d at 1570-71. Because secondary considerations are relevant to obviousness-type double patenting, Teva's argument that statutory obviousness is not at issue is unavailing. (Teva Br. at 1).

Federal courts are not the only ones to find secondary considerations of non-obviousness relevant to obviousness-type double patenting. The Manual of Patent Examining Procedure ("M.P.E.P."), which sets the standards by which the United States Patent and Trademark Office ("P.T.O.") determines the patentability of inventions, states unambiguously that secondary considerations, if present, must be considered in determining whether obviousness-type double patenting is applicable:[2]

> [T]he factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obviousness-type double patenting analysis. These factual inquiries are summarized as follows: . . . .
>
> (D) Evaluate any objective indicia of nonobviousness.
>
> The conclusion of obviousness-type double patenting is made in light of these factual determinations.
>
> M.P.E.P. § 804(II)(B)(1) (Eighth Ed., August 2001) (copy attached hereto as Exhibit 1).

Accordingly, unless objective indicia are considered, the conclusion of obviousness-type double patenting cannot be reached. *Id.*

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[2] Many patent cases are decided on appeal from a rejection of a patent application by the P.T.O. Those cases are easily recognized by their titles, which begin with the prefix "*In re*". Often, evidence of secondary considerations, such as commercial success or the fulfillment of a long-felt need, is unavailable when the application is being considered by the P.T.O. because the invention has not yet been commercially launched. Thus, the fact that secondary considerations are not addressed in a given decision does not mean that they are irrelevant to obviousness-type double patenting.

The authority of the M.P.E.P. is not confined to the United States Patent and Trademark Office. Courts, including the Supreme Court, rely regularly upon the M.P.E.P. *See, e.g., Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 159 n. (1989); *Abbott Labs v. Baxter Pharmaceutical Prods., Inc.*, 334 F.3d 1274, 1280 (Fed. Cir. 2003); *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1365 (Fed. Cir. 2003).

With utter disregard to this authority, Teva asserts "the Federal Circuit has held that such objective indicia are . . . irrelevant to obviousness-type double patenting," citing a solitary footnote in *Geneva Pharmaceuticals, Inc. et al. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1377-78 (Fed. Cir. 2003) (Teva Br. at 2). Teva is wrong. First, all that footnote says is that "[o]bviousness requires inquiry into objective criteria suggesting non-obviousness; nonstatutory double patenting does not." *Id.* at 1378 n.1. The footnote does not *prohibit* inquiry into objective criteria in an obviousness-type double patenting analysis; nor does it suggest, as Teva would have it, that they *are irrelevant* to such an analysis. (Teva Br. at 2). Second, the footnote exists in a legal vacuum. The Federal Circuit cites no authority to support it, and no other Federal Circuit decision has followed it.

Third, contrary to Teva's assertion (Teva Br. at 2, 3), the note is not a "holding"; it is mere *dicta*. As even a cursory reading of the *Geneva* decision would reveal, the Federal Circuit found the claims there invalid for double patenting not because they were obvious in view of the earlier-expiring claims, but because they were *anticipated* by those claims. *Geneva*, 349 F.3d at 1384-85 (claims of '352 and '552 patents invalid for nonstatutory double patenting "because the earlier species within the Crowley claim *anticipates* the later genus" of those claims"; and claims of '720 patent invalid for nonstatutory double patenting because they were inherently "anticipated" by claims of the Fleming patent) (emphasis

added). Both parties agree that, where a finding of double patenting rests solely on anticipation rather than obviousness, secondary considerations of non-obviousness are not relevant. The Federal Circuit in *Geneva* thus had no occasion to examine any secondary considerations of non-obviousness, and no need to decide whether they are relevant in a double patenting context. Nor, indeed, did the district court in that case examine any secondary considerations of non-obviousness. *See Geneva Pharmaceuticals, Inc. et al. v. GlaxoSmithKline PLC,* 213 F. Supp. 2d 597 (E.D. Va. 2002); *Geneva Pharmaceuticals, Inc. et al. v. GlaxoSmithKline PLC*, 189 F. Supp. 2d 377 (E.D. Va. 2002).

Unlike the defendant in *Geneva*, Teva here bases its double patenting allegation on obviousness, not anticipation. (Teva Br. at 1). Thus, for the reasons given above, evidence of secondary considerations is relevant and cannot be ignored. To preclude this evidence, based solely upon Teva's misreading of unsupported dicta in a solitary footnote, would prejudice SKB incurably and would contradict both settled law and the standards of the United States Patent and Trademark Office. Moreover, despite its reliance upon Fed. R. Evid. 403 (Teva Br. at 3), Teva cannot demonstrate any unfair prejudice that would result if the Court were to admit at trial evidence of secondary considerations. Accordingly, the Court should deny Teva's motion.

2. Evidence Of A Compound's Properties Is Not A Secondary Consideration And Cannot Be Precluded

Teva does not stop at merely asserting that evidence of the "real world" indicia of non-obviousness should be precluded; it goes so far as to assert that evidence of lamotrigine's properties is nothing more than another "secondary consideration". Once again, Teva is wrong.

Evidence of a compound's properties is not a secondary consideration of non-obviousness, and should not be precluded. Secondary considerations, as formulated by the Supreme Court, "focus attention on *economic and motivational* rather than *technical* issues". *Graham v. John Deere Co.*, 383 U.S. at 35-36 (emphasis added). Thus, the *Graham* Court did not list properties as a secondary consideration. *Id.* at 17-18. Likewise, the article cited by the *Graham* Court to support the relevancy of secondary considerations does not list properties as a secondary consideration. Richard L. Robbins, *Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity*, 112 U. Pa. L. Rev. 1169 (1964). *See also Comm'r of Patents v. Deutsche Gold-und-Silber-Scheideanstalt Vormals Roessler*, 397 F.2d 656, 663 (D.C. Cir. 1968) ("[N]o court, including the Supreme Court, has ever considered chemical properties to be 'secondary' in the determination of obviousness."); *Warner Jenkinson Co. v. Allied Chem. Corp.*, 477 F. Supp. 371, 393 (S.D.N.Y. 1979) ("[T]he essential unpredictability of the most important properties negates the claim of obviousness. This conclusion is *bolstered* by the various secondary considerations noted by the Supreme Court . . . . ") (emphasis added); *Knoll Pharm. Co. v. Teva Pharmaceuticals USA, Inc.*, 367 F.3d 1381, 1384-85 (Fed. Cir. 2004) (treating unexpected properties as separate from objective criteria like failure of others); *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1468 (Fed. Cir. 1990) (treating unexpected properties as separate from such secondary considerations as commercial success); *Spalding v. Evenflo Companies, Inc. v. Acushnet Co.*, 718 F. Supp. 1023, 1045-46 (D. Mass. 1989) (same).

It is settled law that evidence of a compound's properties is a primary determinant – not a secondary consideration – of non-obviousness. As the Federal Circuit's predecessor, the Court of Customs and Patent Appeals ("C.C.P.A."), has said:

> a compound and all of its properties are inseparable; they are one and the same thing . . . . [A] formula is not a compound and while it may serve in a claim to *identify* what is being patented, as the metes and bounds of a deed identify a plot of land, the *thing* that is patented is not the formula but the compound identified by it. And the patentability of the thing does not depend on the similarity of its formula to that of another compound but of the similarity of the former compound to the latter. *There is no basis in law for ignoring any property in making such a comparison. In re Papesch*, 315 F.2d 381, 391 (C.C.P.A. 1963) (emphasis added).

It is also beyond dispute that evidence of properties is relevant to obviousness-type double patenting. *See In re Gladrow*, 406 F.2d 1376, 1384-85 (C.C.P.A. 1969) (reversing finding of obviousness-type double patenting as to certain claims based on evidence of invention's unexpected properties). Indeed, in the instant case, the P.T.O. itself called upon the patent applicants to submit evidence of lamotrigine's unexpected properties, and then considered that very evidence in granting the patent.

Teva cites no authority which holds that unexpected properties are irrelevant to obviousness-type double patenting. The footnote in *Geneva* does not help Teva. First, the footnote does not so much as suggest that properties are "secondary considerations". Second, even if the footnote could somehow be read that way, the panel decision in *Geneva* cannot overrule *Gladrow* or *Papesch*, as the Federal Circuit is bound to follow the decisions of the C.C.P.A. and can only overrule them when sitting *en banc*. *See South Corp. v. United States*, 690 F.2d 1368, 1370-71 (Fed. Cir. 1982). Third, the Federal Circuit itself long has considered evidence of unexpected properties to be relevant to obviousness-type double patenting. *See, e.g., Ortho Pharmaceutical Corp. v. Smith*, Civ. A. No. 90-0242, 1990 WL 121353 (E.D. Pa. Aug. 17, 1990), *aff'd* 959 F.2d 936 (Fed. Cir. 1992) (finding no obviousness-type double patenting where invention compounds were unexpectedly more

potent); *In re Emert*, 124 F.3d 1458, 1462 (Fed. Cir. 1997) (finding claimed invention invalid for obviousness-type double patenting "[a]bsent some indication of unexpected properties").

The other cases that Teva cites for the proposition that unexpected properties are "secondary considerations" are similarly unavailing.[3] In none of those cases was the court faced with the issue of whether unexpected properties are secondary considerations. Their mischaracterization of unexpected properties as secondary considerations thus is mere *dicta.* Furthermore, the decisions Teva cites cannot – and do not purport to – overrule the explicit mandate of the Supreme Court that secondary considerations shall focus on "economic and motivational", rather than "technical", issues.[4] *Graham v. John Deere Co.*, 383 U.S. at 35-36. Finally, the decisions Teva relies on are contradicted by *Deutsche Gold*, 397 F.2d at 663, which *holds* that unexpected properties are not secondary considerations, and by many other cases in which unexpected properties properly were not regarded as secondary considerations. *See e.g., Knoll Pharm.*, 367 F.3d at 1384-85; *Hewlett-Packard Co.*, 909 F.2d at 1468; *Spalding*, 718 F. Supp. at 1045-46.

There can be no reasonable dispute that evidence of lamotrigine's unexpected properties is relevant to obviousness-type double patenting and should be considered by the Court. To preclude such evidence at trial would be wrong and prejudicial, and would deprive

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[3] *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998); *Apple Computer, Inc. v. Articulate Sys., Inc.*, 234 F.3d 14 (Fed. Cir. 2000); *Zeller Plastik, Koehn, Grabner & Co. v. Joyce Molding Corp.*, 698 F. Supp. 1204 (D.N.J. 1998); *Specialty Composites v. Cabot Corp.*, 845 F.2d 981 (Fed. Cir. 1998).

[4] Also, *Specialty Composites* relies on *United States v. Adams*, 383 U.S. 39, 51-52 (1966) for the proposition that unexpected properties provide objective evidence of non-obviousness. 845 F.2d at 991. However, the *Adams* Court did not even address that issue, much less hold that unexpected properties are objective indicia.

the Court of the benefit of having before it the very type of evidence accepted by the P.T.O. in granting the patent. Accordingly, the Court should deny Teva's motion.

CONCLUSION

For the foregoing reasons, Teva's motion *in limine* to preclude evidence of objective indicia of non-obviousness as irrelevant under Fed. R. Evid. 401 to 403 must be denied.

Dated: November 8, 2004

Respectfully submitted,

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EXHIBIT 1

Manual of PATENT EXAMINING PROCEDURE

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B. Nonstatutory Double Patenting

A rejection based on nonstatutory double patenting is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent. *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re White*, 405 F.2d 904, 160 USPQ 417 (CCPA 1969); *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); *In re Sarett*, 327 F.2d 1005, 140 USPQ 474 (CCPA 1964).

1. Obviousness-Type

In determining whether a nonstatutory basis exists for a double patenting rejection, the first question to be asked is — does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent? If the answer is yes, then an "obviousness-type" nonstatutory double patenting rejection may be appropriate. Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is **not patentably distinct** from the subject matter claimed in a commonly owned patent when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent. See *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 58 USPQ2d 1865 (Fed. Cir. 2001); *Ex parte Davis*, 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000).

A double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103" except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Since the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection, the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis. These factual inquiries are summarized as follows:

(A) Determine the scope and content of a patent claim and the prior art relative to a claim in the application at issue;

(B) Determine the differences between the scope and content of the patent claim and the prior art as determined in (A) and the claim in the application at issue;

(C) Determine the level of ordinary skill in the pertinent art; and

(D) Evaluate any objective indicia of nonobviousness.

The conclusion of obviousness-type double patenting is made in light of these factual determinations.

Any obviousness-type double patenting rejection should make clear:

(A) The differences between the inventions defined by the conflicting claims — a claim in the patent compared to a claim in the application; and

(B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim in issue is an obvious variation of the invention defined in a claim in the patent.

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* recognized "that it is most difficult, if not meaning-